

# **Exhibit K**

## **TVT SECUR Single-Incision Sling After 5 Years of Follow-Up: The Promises Made and the Promises Broken**

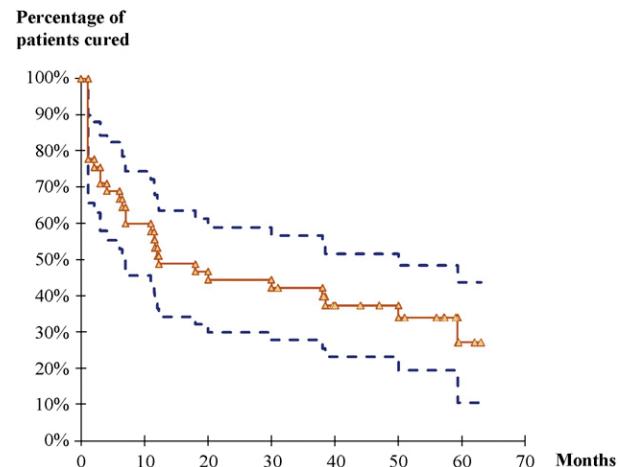
Traditional midurethral sling (MUS) implantation is the main option for surgical management of stress urinary incontinence (SUI) in women, based on high levels of evidence and long follow-up data [1]. Although many short-term studies have presented TVT SECUR as a promising alternative to MUS, the efficacy of this device after 3 yr of follow-up remains unknown. Our objective was to provide data on the efficacy and safety of TVT SECUR after 5 yr of follow-up.

We conducted a prospective evaluation of 45 consecutive patients who underwent TVT SECUR implantation for SUI in a tertiary reference center between September 2006 and March 2007. We provided the study design and patient characteristics of this case series in a previous report [2]. Our results were updated after a long-term evaluation in 2011, integrating the results of the Urinary Symptom Profile (USP) [3] validated questionnaire, assessment of pad use, results of the Patient's Global Impression of Improvement (PGI-I) questionnaire [4], use of medical treatment for urinary tract symptoms (if any), occurrence of adverse events, and rehospitalization in the past 5 yr linked to the procedure. **The primary end point focused on efficacy.** We evaluated the number of patients cured at last follow-up, defined as no stress-related leakage, using no pads, and satisfied with the treatment (PGI-I score: 1 or 2). Other cases were analyzed as simple failure or failure with complementary salvage therapy by MUS implantation. The primary end point (percentage of patients cured) was established via a survival analysis (using the Kaplan-Meier method), where the event was the recurrence of SUI during follow-up.

Patients' characteristics at baseline were described previously [2]. Ten patients were not part of the 2011 evaluation, but they were integrated in the present analysis because last follow-up information was >31 mo since implantation in all cases. The median follow-up for the present evaluation was 59 mo (interquartile range [IQR]: 57–61).

**At last follow-up, only 14 of 45 patients (31%) were cured** (ie, reported no leakage, high satisfaction, and no pad use). Figure 1 shows the pattern of recurrence of the symptoms during follow-up using the Kaplan-Meier survival without recurrence curve. We noted that SUI recurrence occurred continuously over time during follow-up.

From the original study cohort, 13 patients (29%) were treated with the traditional midurethral sling because of failure of the TVT SECUR 8 mo (IQR: 4–12) after mini-sling implantation. Three underwent transobturator tape implantation and were free of SUI symptoms at last follow-up, but they all had overactive bladder (OAB) wet requiring pad use. However, these three patients had OAB prior to the first sling implantation. Ten patients underwent a tension-free vaginal tape procedure; six of them were cured, three had OAB wet symptoms requiring pad use, and one had voiding difficulties.



**Fig. 1 – Kaplan-Meier analysis of recurrence of stress urinary incontinence symptoms during follow-up.**

The 18 patients with secondary failure was the most heterogeneous group. In the vast majority of cases, recurrent SUI symptoms were the reason for pad use, but four of them were wearing pads only because of relatively severe wet OAB (USP OAB subscore >9 of 21 points).

No preoperative factor (age, maximal urethral closure pressure, incontinence severity, associated conditions) was significantly associated with the main outcome of the study. No severe adverse event was recorded after 4.5 yr of follow-up. The main secondary effect of the procedure was occurrence of OAB symptoms. Seven patients described at least two urinary tract infections during follow-up, and two patients had mild temporary voiding difficulties after the procedure.

Although the vast majority of the literature reports only short-term studies for TVT SECUR (<2 yr of follow-up) with inconsistent results, the present results show that TVT SECUR results worsen with time, even several years after the operation. Although obviously limited by its single-arm design, small number of patients, and mainly subjective nature of the outcome criteria, our study confirms the need for long-term reports in the field of SUI [5].

**In our experience, the TVT SECUR device definitely did not stand the test of time, with a 31% success rate after 4.5-yr of follow-up, and it should not be considered a valuable option for SUI management unless supplementary data are provided regarding its long-term outcome.**

**Conflicts of interest:** François Haab is a consultant for Gynecare. The other authors have nothing to disclose.

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June 26, 2012

Published online ahead of print on July 4, 2012

<http://dx.doi.org/10.1016/j.eururo.2012.06.054>

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